REMARKS

Claims 1-19, 24-33 and 35-37 were pending in the subject application. By this amendment, Claims 3-4 and 24 have been canceled without prejudice or disclaimer; Claims 1-2, 5-7, 9, 11-14, 16-19, 25, 27, 33, 35 and 37 have been amended; and new Claim 41 has been added. Accordingly, upon entry of the amendment, Claims 1-2, 5-19, 25-33, 35-37 and 41 will be pending and under examination.

Applicants maintain that the amendments to the claims do not raise an issue of new matter. Support for the amendments can be found at least in the previous version of the claims. Accordingly, entry of the amendments is respectfully requested.

Rejections under 35 U.S.C. §112, First Paragraph

1. Claims 1-3 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement for the full breadth of the claims. Claims 1-2 have herein above been amended to recite that the tumor is a "melanin-containing tumor..." and that the cellular component released by the tumor cell is "melanin." Claim 3 has herein above been canceled. Reconsideration and withdrawal of this rejection are respectfully requested.

2. Claims 1-19, 25-33 and 35-37 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement for the full breadth of the claims. In particular, the Examiner indicated that the claims are only enabled for use of the antibody 6D2 in view of a 1954 publication by Mason et al. (Cancer Research 14: 648-650). The Examiner indicated that Mason et al. teach that administration of a radiolabeled anti-melanin antibody to mice bearing melanin-containing melanomas resulted in no significant localization of radioactivity.

Applicants respectfully traverse this rejection.

Applicants note that the teachings of Mason et al. reflect the technology of a half century ago and not the state of the art technology readily available to the skilled artisan

at the time the subject application was filed. First, Mason et al. did not use a monoclonal antibody (this technology was first described in 1975) but only anti-melanin gamma globulin from sera. In rabbit polyclonal antibody the amount of melanin-specific antibody is only a small fraction of the total immunoglobulin pool. Monoclonal antibodies are more specific and sensitive than polyclonal gamma-globulins. Second, Mason et al. used an outdated radiolabeling technique that resulted in extremely low specific activity of the radiolabeled antibody, i.e. 10 μCi/0.75 mg protein (~13 μCi/mg protein). In comparison, much higher specific activities are routinely achievable with modern radiolabeling techniques (for example, 15 mCi/mg for $^{188}$Re-6D2 and 4 mCi/mg for $^{99m}$Tc-6D2; see page 14866, right column, of Dadachova et al. PNAS 101: 14865-70, 2004, copy of article attached hereto). As a result of the extremely low specific activity of their labeled globulin, Mason et al. effectively saturated all possible binding sites on extracellular melanin in the tumor with an enormous excess of unlabeled globulin. Hence, the methodological limitations of low activity in labeling combined with only a minute amount of specific antibody can easily explain the inability of Mason et al. to obtain significant localization of radioactivity at the melanoma.

Reconsideration and withdrawal of this rejection are respectfully requested.

3. Claim 24 is rejected under 35 U.S.C. §112, first paragraph, as not enabled because the specification does not provide evidence that the claimed biological material is known and readily available to the public and reproducible from the written description. Claim 24 has herein above been canceled, thereby rendering this rejection moot.

Rejections under 35 U.S.C. §102(b)

Claim 2 is rejected as anticipated by Thorpe et al. (U.S. Patent No. 6,342,221).

Claims 1-3 are rejected as anticipated by Goldenberg (U.S. Patent No. 4,460,561).

Claims 1-2 have herein above been amended to recite that the tumor is a "melanin-containing tumor..." and that the cellular component released by the tumor cell

is "melanin." Claim 3 has herein above been canceled. Applicants maintain that the cited references do not anticipate the pending claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 1 and 3 are rejected as being unpatentable over Thorpe et al. (U.S. Patent No. 6,342,221) in view of Goldenberg (U.S. Patent No. 4,460,561).

Claim 1 has herein above been amended to recite that the tumor is a "melanin-containing tumor..." and that the cellular component released by the tumor cell is "melanin." Claim 3 has herein above been canceled. Applicants maintain that the cited references do not teach or suggest the pending claims. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

## CONCLUSIONS

In view of the remarks and amendment made hereinabove, reconsideration and withdrawal of the rejections set forth in the February 28, 2006 Office Action and passage of the pending claims to allowance are respectfully requested. If there are any minor matters preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

A check for $990.00 is enclosed for the following fees for a small entity: 1) $60.00 fee for a one month extension of time, 2) $180.00 multiple dependent claim fee; and 3) $750.00 fee for 30 claims in addition to the 37 claims originally paid for ($25.00 per excess claim). No other fee is deemed necessary in connection with the filing of this reply. However, if any other fee is required with this submission or to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Any overpayment may be credited to Deposit Account No. 01-1785.

Respectfully submitted,

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